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AMENDMENT TO THE DRAWINGS

In **Figure 9** on the replacement drawing sheet 6/6 that is included in this Reply, the extraneous section line 2-2 has been deleted.

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REMARKS

Request for Entry of Amendment Under 37 CFR § 1.116

Entry of the present amendments is respectfully requested. It is believed that these amendments are necessary to correct the text and drawings for either allowance or appeal.

Amendment to the Description

A paragraph on page 3 of the description as originally filed has been amended to correct a typographical error in which the absorbent core was erroneously identified by the reference numeral 26 rather than the correct numeral 28 as elsewhere in the text and drawings.

A paragraph on page 4 of the description as originally filed has been amended to correct a typographical error by changing "or" to "of" in the phrase "the specific gravity ~~or~~ of urine".

A paragraph on page 7 of the description as originally filed has been amended to correct a typographical error by changing "e.g." to "i.e." in the phrase "various ionic strengths and specific gravities, ~~e.g.~~ i.e., various threshold values".

A paragraph on page 9 of the description as originally filed has been amended to correct a typographical error in which the fluid transport element was erroneously identified by the reference numeral 100 rather than the correct numeral 160 as in Figure 9 of the drawings.

Amendment to the Drawings

In Figure 9 on drawing sheet 6/6, the extraneous section line 2-2 has been deleted in light of the fact that no section view corresponding to this section line was provided in the drawings.

Claim Rejections Under 35 U.S.C. § 102

Claims 1, 2, 4 through 12, and 14 through 20 were again rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,515,194 to Neading *et al.*

The statements of rejection were repeated from the previous Office Action. These rejections are again hereby respectfully traversed on the ground that it was not shown in the Office Action that the cited reference teaches every element of any of the rejected claims.

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Every one of the claims contains the term "threshold". The definition of "threshold" is:

- "[t]he point that must be exceeded to begin producing a given effect or result or to elicit a response" (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000);
- "a level, point, or value above which something is true or will take place and below which it is not [true] or will not [take place]" (Merriam-Webster® Online Dictionary); and/or
- "the level or point at which...something starts to happen" (Cambridge Advanced Learner's Dictionary).

Specifically, every one of the claims contains the limitation that the visible signal is provided when the urine ionic strength reaches a value corresponding to a threshold of the urine specific gravity. Thus, the wording of the claims explicitly conveys to the reader that:

- the value of the ionic strength corresponding to the threshold of the specific gravity must be exceeded to begin producing the visible signal or to elicit the visible signal (using the definition from The American Heritage® Dictionary);
- the value of the ionic strength corresponding to the threshold of the specific gravity is the value at which the visible signal will be provided and below which it will not be provided (using the definition from the Merriam-Webster® Online Dictionary); and/or
- the value of the ionic strength corresponding to the threshold of the specific gravity is the point at which the visible signal starts to be provided (using the definition from the Cambridge Advanced Learner's Dictionary).

In addition, every one of the claims contains the limitation that the threshold of the urine specific gravity is predetermined. The definition of "predetermine" is:

- "to determine, decide, or establish in advance (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000);
- "to determine beforehand" (Merriam-Webster® Online Dictionary); and/or
- "to decide or arrange something at an earlier time" (Cambridge Advanced Learner's Dictionary).

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Thus, the wording of the claims explicitly conveys to the reader that:

- the threshold of the specific gravity is determined, decided, or established in advance (using the definition from The American Heritage® Dictionary);
- the threshold of the specific gravity is determined beforehand (using the definition from the Merriam-Webster® Online Dictionary); and/or
- the threshold of the specific gravity is decided at an earlier time (using the definition from the Cambridge Advanced Learner's Dictionary).

In other words, the wording of the claims clearly conveys to the reader that the *threshold* of the urine specific gravity is *determined in advance* and that the visible signal is provided only when the urine ionic strength is in a range that starts at a certain value corresponding to that threshold and extends to higher values, and is not provided when the urine ionic strength is below that range. This meaning of the claims is just as clear as if the preceding wording in this paragraph had been written into the claims because the definitions of the terms *threshold* and *predetermined* are completely clear and unambiguous.

In contrast, the Neading *et al.* reference fails to disclose the concept of providing a visible signal when any selected property exceeds a value corresponding to any predetermined threshold of any correlated property and not providing the signal when the property is below that value. Instead, as repeatedly stated in the reference, beginning in the title, the invention of Neading *et al.* is a wetness indicator, *i.e.*, something that indicates the *presence* of a liquid rather than any level or value of any property of that liquid. Consistent with this, the Neading *et al.* reference explicitly discloses that this wetness indicator is intended to provide:

- “an immediate indicator to the person caring for the small child that the child has excreted waste and soiled the diaper” (4:28-30) in the form of
- “a visible response to the presence of fluid” (Abstract, last line) and
- “a visible change...in response to the presence of fluid, such as urine” (3:50-52), *etc.*

In fact, the very concept of requiring a parameter to exceed a threshold before providing a signal is inconsistent with the explicitly stated objectives of Neading *et al.*, because requiring a parameter to exceed a threshold would mean that the visible signal would not be provided after

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all urinations, but instead would be provided only after the excretion of urine in which the selected parameter exceeded the threshold. In other words, limiting the response of the wetness indicator of Neading *et al.* to a range above a threshold would render it unsuitable for its intended purpose.

Furthermore, the statement in the Final Office Action that "[t]he indicator disclosed by Neading will change color or otherwise exhibit a change at a specific level of specific gravity" is not supported by the disclosure of the Neading *et al.* reference. No threshold for any property or parameter is mentioned in the reference. In fact, no value or level of any property or parameter, of the nature of a threshold or otherwise, is mentioned in the reference. Instead, a long list of physical and chemical characteristics that can elicit the desired response appears at column 4, line 1 through 8, but nothing is mentioned regarding "setting a trigger" such that the response will occur in relation to a threshold. A specific example of using litmus paper as a urinary indicator appears immediately following this list, but again nothing is mentioned regarding a threshold, such as a particular pH value. Given the explicitly stated objective of the wetness indicator of providing an immediate indicator that a child has soiled a diaper, regardless of the level or value of any property of the excreta, this omission of any mention of a threshold makes perfect sense, as discussed above.

Additionally, the following points in the Final Office Action bear comment, just as they did in the previous Reply to the first Office Action in which they appeared.

In the Final Office Action, **Claim 2** was again rejected on the basis that the indicator of Neading *et al.* provides a qualitative indication of the specific gravity. The relevant limitation in **Claim 2** is not merely that the claimed dehydration indicator provides a qualitative indication of a urine specific gravity, but that it provides a qualitative indication of a urine specific gravity associated with dehydration and, because **Claim 2** depends from **Claim 1**, that it provides this indication in a range that starts at a certain value of the ionic strength corresponding to a predetermined threshold of the specific gravity and extends to higher values, and, by definition, does not provide this indication when the ionic strength is below that range. In contrast, nothing regarding dehydration is mentioned in the Neading *et al.* reference and, as discussed above, nothing regarding a threshold is mentioned.

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In the Final Office Action, Claims 3 and 13 were again referenced in the context of a qualitative indication of specific gravity. However, Claims 3 and 13 do not mention a qualitative indication, i.e., do not contain such a limitation. Instead, these two claims are directed to a translucent cover. Therefore, the references to a qualitative indication do not make sense with respect to these two claims.

In the Final Office Action, Claims 5, 6, 19, and 20 were again rejected on the basis that the indicator of Neading *et al.* comprises an indicium, the indicium being a color change, and it was stated that a color change is an indicium resulting from a chemical reaction. However, the definition of an indicium is "a distinctive mark" and the definition of a mark is "a written or printed symbol" (both from Merriam-Webster® Online Dictionary). A color change might indicate something and might be called an "indicator" of something, but it is not a distinctive written or printed symbol and is therefore not an indicium.

In the Final Office Action, Claims 8 and 14 were again rejected on the basis that the indicator of Neading *et al.* is covered by a semipermeable membrane, the semipermeable membrane being element 14B. It was also stated that the indicator is disposed on the transport layer 14. Finally, it was stated that the transport layer is a fluid-permeable material and therefore fulfills the claim limitation of a semipermeable membrane. However, this characterization of the disclosure of Neading *et al.* is inaccurate, for at least the following reasons.

1. The wetness indicator 16 of Neading *et al.* is not covered by element 14B, which is the central portion of the fluid transport layer 14. Instead, the wetness indicator 16 of Neading *et al.* is exposed, i.e., not covered by any other layer, and is therefore visible at the peripheral edge 14A (column 2, lines 4 and 56; column 3, line 62; column 4, lines 45, 49, and 67; column 5, line 23; column 6, lines 6, 17, 23, and 29; Figures 1, 3). This exposure and visibility of the indicator "along substantially all portions of the peripheral edge" is a key feature of the invention (column 3, line 59 through column 4, line 1).
2. In fact, Neading *et al.* explicitly disclose that the indicator 16 is located at the peripheral edge 14A of the fluid transport layer 14 (column 3, lines 57-60; Figures 1, 3), not in the central portion 14B, which is "spaced inwardly from the peripheral edge 14A" (column 3, lines 33-35; Figures 1, 3, 5, 6, 7).

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3. The wetness indicator 16 being disposed on the transport layer 14 does not mean that it is covered by anything.
4. According to the Merriam-Webster® Online Dictionary, the meaning of "semipermeable" is "partially but not freely or wholly permeable; *specifically* : permeable to some usually small molecules but not to other usually larger particles <a *semipermeable* membrane>". Thus, merely being "fluid-permeable" does not make the transport layer 14 of Neading *et al.* semipermeable. In addition, the special distinction of a semipermeable membrane is well-known in the art.

In summary with regard to the rejections of Claims 1, 2, 4 through 12, and 14 through 20 under 35 USC § 102(e), the cited Neading *et al.* reference fails to teach every element of any of the rejected claims. Accordingly, it is respectfully requested that the rejections of these claims be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 3 and 13 were again rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,515,194 to Neading *et al.* in view of U.S. Patent No. 5, 947,943 to Lee.

The statements of rejection were repeated from the previous Office Action. These rejections are again hereby respectfully traversed on the ground that the requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness have not been met.

As noted above, the Neading *et al.* reference fails to teach or suggest all of the limitations of independent Claims 1 and 10, from which Claims 3 and 13 respectively depend. The Lee reference likewise fails to teach or suggest any of the missing limitations and thus fails to remedy the shortcomings of the Neading *et al.* reference.

In particular, these claims were again rejected on the basis that the Neading *et al.* reference discloses all aspects of the claimed invention but remains silent with respect to the outer cover, that Lee discloses a translucent outer cover, and that it would have been obvious to make the outer cover of Neading *et al.* translucent as taught by Lee, "so that the indicator may be easily viewed without removing the article". In addition, it was stated that "[m]odification of the article

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of Neading in view of this teaching [of Lee] would allow the entire article of Neading to be covered by the backsheet while the indicator remains visible. Thus, Lee teaches an improvement to Neading”.

However, this allegation is not only unfounded, but directly contradictory to the explicit disclosure of Neading *et al.*, in at least the following ways:

1. The proposed modification to the structure taught by Neading *et al.* is not necessary to achieve the objective of making the indicator visible because the wetness indicator of Neading *et al.* is already visible by dint of being exposed. In fact, this is the main point of their invention, as discussed above in this Reply.
2. The Neading *et al.* reference explicitly teaches away from reapplying the structure taught by Lee, to wit:

In the Lee patent, a wetness-indicating material is disposed on an interior-facing side of a back sheet of a diaper. The Lee wetness-indicating material changes its appearance after it is exposed to water. The Lee patent, however, appears to be unduly complex and costly for achieving this objective” (column 1, lines 45 and 46).

Thus, the proposed modification to the structure taught by Neading *et al.* is unnecessary. Furthermore, modifying the structure in precisely the way that Neading *et al.* explicitly considered and rejected can hardly be considered an improvement.

Therefore, the cited prior art references, either singly or in combination, fail to teach or suggest all of the limitations of the rejected claims. The references similarly fail to provide any suggestion or motivation to modify or combine their teachings; in fact, the Neading *et al.* reference explicitly teaches away from using the teachings of the Lee reference. Furthermore, the modification proposed in the Office Action is not necessary to achieve the objective stated in the Final Office Action because the structure of Neading *et al.* already achieves that objective.

Thus, the requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness have not been met with respect to either of the rejected claims. Accordingly, it is respectfully

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requested that the rejections of Claims 3 and 13 under 35 USC § 103(a) be reconsidered and withdrawn.

Summary of this Response

No new matter has been added in this response.

Several typographical errors in the description have been corrected.

An error in a drawing figure has been corrected.

The rejections of claims have been traversed and argued. In light of these remarks, it is respectfully requested that the rejections be reconsidered and withdrawn and that the pending claims be allowed.

Respectfully submitted,

By: Michael P. Hayden

Michael P. Hayden

Registration No. 48,433

Phone: (513) 634-5801

Fax: (513) 945-2958 or (513) 634-3499

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Customer No. 27752